



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/755,996 | 01/13/2004 | Peter M. Bonutti | 780-A03-021-5 | 1472 |

33771 7590 09/10/2007
PAUL D. BIANCO: FLEIT, KAIN, GIBBONS,
GUTMAN, BONGINI, & BIANCO P.L.
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

| |
|----------|
| EXAMINER |
|----------|

HOFFMAN, MARY C

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3733

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

09/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/755,996

Applicant(s)

BONUTTI, PETER M.

Examiner

Mary Hoffman

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-10, 13, 15, 19, 21, 22 and 25-40 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-10, 13, 15, 19, 21, 22, 25-32 and 34-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/13/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

It is noted that comparison of the claims with elected species, Figure 9, and the specification shows, however, that the species of Figure 9 does not have means for changing from the wide position to the narrow position as required in claims 33.

Claim 33 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1, 4-10, 13, 15, 19, 21-22 and 30-40 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 30, lines 3-4, applicant positively recites part of a human, i.e. "abutting the first bone...abutting the second bone". In claim 40, lines 1-2, applicant positively recites part of a human, i.e. "the implant is connected to only one of the bones". Thus claims 1, 4-10, 13, 15, 19, 21-22 and 30-40 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive

Art Unit: 3733

property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8-9, 13, 19, 30-32, 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Stone (U.S. Patent No. 6,008,433).

Stone discloses an implantable device capable of reversibly changing a spatial relationship between a first bone and a second bone from a wide position to a narrow position, comprising a first surface capable of abutting the first bone in the wide position and the narrow position; a second surface capable of abutting the second bone in the wide position and the narrow position; and a body interconnecting the first surface and the second surface, the first surface maintaining an equal distance from the second surface when moving from the wide position to the narrow position (the device shown in FIG. 3C and 4A is capable of being inserted on its side and then be rotated 90 degrees). The implantable device is capable of being rotated via the pin about an axis to move between the wide position and the narrow position and not move longitudinally

Art Unit: 3733

along the axis when moving from the wide position to the narrow position. The device comprises a bone growth promoting material (col. 6, lines 60-61). The implant is adapted to one connected to only one of the bones. The first surface tapers to form a pointed edge with the second surface. A side surface corresponding to the outer surface of the bone connects the first and second surfaces. The body has an open cellular structure to provide cavities in which bone can grow through (col. 6, lines 34-36). The body is made of a biocompatible metallic material (col. 6, lines 44-46). At least some of the cavities contain a bone growth promoting material (col. 7, lines 8-14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-35 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635).

Stone discloses the claim invention except for the device being coated with a bone growth promoting material and the bone growth promoting material includes a bone morphogenic protein.

Art Unit: 3733

Michelson discloses using a coating of bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, in order to promote bioactive fusion (col. 9, lines 20-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with the coating of Michelson in order to promote bioactive fusion.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635) further in view of Jefferies (U.S. Patent No. 4,394,370).

Stone in view of Michelson discloses the claimed invention except for the coating being apatite compositions such as demineralized bone powder and collagen.

Jefferies teaches both demineralized bone powder and collagen as materials to induce the formation of osseous tissue (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the coating of the Stone in view of Michelson to include demineralized bone powder and collagen in view of Jeffries, since those materials are well known in the art of bone fusion as materials to induce the formation of osseous tissue.

Claims 15, 36-38, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Henderson (U.S. Patent No. 6,066,175).

Art Unit: 3733

Stone discloses the claim invention except for a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and screws angularly disposed in the channels and nested in the side surface.

Henderson et al. disclose an implantable device including a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and first and second screws angularly disposed in the channels and nested in the side surface in order to in order to provide means of attachment to the bone (ref. #48, 49, FIGS. 8-9, col. 9, lines 29-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and first and second screws angularly disposed in the channels and nested in the side surface in view of Henderson in order to provide means of attachment to the bone.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Zdeblick et al. (U.S. Patent No. 5,669,909).

Stone discloses the claimed invention except for using tantalum.

Zdeblick et al. teaches using porous tantalum in implants to allow bone ingrowth.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone using tantalum in view of Zdeblick et al. to allow bone ingrowth.

Claims 25-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635) and Henderson et al. (U.S. Patent No. 6,066,175).

Stone discloses an implantable device for changing the spatial relationship between first and second bones comprising a body (see FIG. 4A), wherein the body includes bone-contacting first and second major planar surfaces, and a side surface there between and wherein one major surface tapers to form a pointed edge with the other major surface. The body has an open cellular structure to provide cavities in which bone can grow through (col. 6, lines 34-36). The body is made of a biocompatible metallic material (col. 6, lines 44-46). At least some of the cavities contain a bone growth promoting material (col. 7, lines 8-14). A portion of the side surface has a configuration corresponding to at least a section of an outer side surface of one of the first and second bones.

Stone discloses the claim invention except for the device being coated with a bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, and a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and screws angularly disposed in the channels.

Michelson discloses using a coating of bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, in order to promote bioactive fusion (col. 9, lines 20-24).

Art Unit: 3733

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with the coating of Michelson in order to promote bioactive fusion.

Henderson et al. disclose an implantable device including a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and first and second screws angularly disposed in the channels in order to in order to provide means of attachment to the bone (ref. #48, 49, FIGS. 8-9, col. 9, lines 29-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and first and second screws angularly disposed in the channels in view of Henderson in order to provide means of attachment to the bone.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635), and Henderson et al. (U.S. Patent No. 6,066,175) further in view of Zdeblick et al. (U.S. Patent No. 5,669,909).

Stone in view of Michelson and Henderson et al. discloses open cellular and biocompatible material, including metals, but does not specifically disclose tantalum.

Zdeblick et al. teaches using porous tantalum in implants to allow bone ingrowth.

Art Unit: 3733

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone in view of Michelson and Henderson et al. using tantalum in view of Zdeblick et al. to allow bone ingrowth.

Response to Arguments

Applicant's arguments filed 06/12/2007 are not persuasive because it does not appear to address the rejection of claims 25-27 and 29 under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635) and Henderson et al. (U.S. Patent No. 6,066,175), and the rejection of claim 28 under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635), and Henderson et al. (U.S. Patent No. 6,066,175) further in view of Zdeblick et al. (U.S. Patent No. 5,669,909).

It is noted that Applicant has not provided arguments/explanations stating how the current claims 25-29 are distinguished from the prior art combinations cited in the previous rejection mailed 03/12/2007. In the Non-final rejection mailed 03/12/2007, claims 25-27 and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stone in view of Michelson and Henderson et al. combination. However, applicant neither mentioned these combinations in the formal response nor pointed out how the amended claims are distinguishable over the prior art combination. Similarly, Applicant did not properly respond to the rejection of claim 28, which was rejected under 35 U.S.C. 103(a) as being unpatentable over Stone in view of Michelson, and Henderson

Art Unit: 3733

et al. further in view of Zdeblick et al. Thus, Applicant's arguments fail to comply with 37 CFR 1.111 (b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. In addition, Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. (See 37 CFR 1.111(b)(c) below).

37 CFR 1.111(b)(c)

(b) In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to the Office action. The reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. If the reply is with respect to an application, a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated. The applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section.

(c) In amending in reply to a rejection of claims in an application or patent under reexamination, the applicant or patent owner must clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. The applicant or patent owner must also show how the amendments avoid such references or objections

In response to applicant's argument that the device of Stone is not intended to change the spatial relationship of bones, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Art Unit: 3733

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Stone, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Applicant's other arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

The rejections are deemed proper.

Conclusion

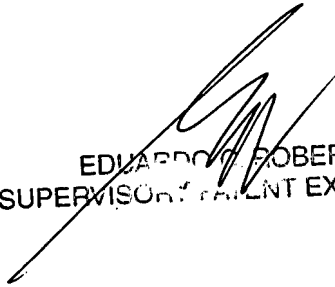
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO ROBERT
SUPERVISORY PATENT EXAMINER